office to charge the necessary fee for an extension of time and for the RCE to Deposit Account No. 05-0840 in the name of Eli Lilly and Company.

Please amend the subject Application as follows:

In the Claims:

Cancel claims 70-121; and add Claims 122-183.

122. A method of normalizing blood glucose comprising administering to the lungs of a patient in need thereof a dipetidyl peptidase IV protected glucagon-like peptide-1 (GLP-1) molecule selected from the group consisting of GLP-1 analogs and GLP-1 derivatives.

123. The method of **Claim 122**, wherein the GLP-1 molecule has an amino acid sequence of a formula:

R_1-X-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Val-Ser-Ser-Tyr-Leu-Y-Gly-Gln-Ala-Ala-Lys-Z-Phe-Ile-Ala-Trp-Leu-Val-Lys-Gly-Arg-R_2

(SEQ ID NO:1)

wherein:

R_1 is selected from the group consisting of L-histidine, D-histidine, desamino-histidine, 2-amino-histidine, beta-hydroxy-histidine, homohistidine, alpha-fluoromethyl-histidine, and alpha-methyl-histidine;

X is selected from the group consisting of Gly, Val, Thr, Ile, and alpha-methyl-Ala;

Y is selected from the group consisting of Glu, Gln, Ala, Thr, Ser, and Gly;

Z is selected from the group consisting of Glu, Gln, Ala, Thr, Ser, and Gly; and

R_2 is selected from the group consisting of NH_2, and Gly-OH.

124. The method of **Claim 123**, wherein the GLP-1 molecule is selected from the group consisting of Gly^8-GLP-1(7-36)NH_2, Val^8-GLP-1(7-37)OH, alpha-methyl-Ala^8-GLP-1(7-36)NH_2, and Gly^8-Gln^{21}-GLP-1(7-37)OH.

125. The method of **Claim 124,** wherein the GLP-1 molecule is Val^8-GLP-1(7-37)OH or Gly^8-GLP-1(7-37)OH.

126. The method of **Claim 125**, wherein the GLP-1 molecule is Val^8-GLP-1(7-37)OH.

127. The method of **Claim 126**, wherein the GLP-1 molecule is Gly^8-GLP-1(7-37)OH.

128. The method of **Claim 123**, wherein the GLP-1 molecule is in the form of a dry powder.

129. The method of **Claim 128**, wherein the dry powder has a particle size of about 10 microns mass median aerodynamic diameter.

130. The method of **Claim 129**, wherein the dry powder has a particle size of less than 10 microns mass median aerodynamic diameter.

131. The method of **Claim 130**, wherein the dry powder has a particle size of about 1 to about 5 microns mass median aerodynamic diameter.

132. The method of **Claim 131**, wherein the dry powder has a particle size of about 2 to about 3 microns mass median aerodynamic diameter.

133. The method of **Claim 128,** wherein the GLP-1 molecule is delivered from an inhalation device suitable for pulmonary administration and capable of depositing the GLP-1 molecule in the lungs of the patient.

134. The method of **Claim 133**, wherein the device is selected from the group consisting of a nebulizer, a metered-dose inhaler, a dry powder inhaler, and a sprayer.

135. The method of **Claim 134**, wherein the device is a sprayer or a dry powder inhaler.

136. The method of **Claim 135**, wherein an actuation of the device administers about 40 μg to about 4,000 μg of the GLP-1 molecule.

137. The method of **Claim 136**, wherein an actuation of the device administers about 80 μg to about 2,000 μg of the GLP-1 molecule.

138. The method of **Claim 137**, wherein an actuation of the device administers about 160 μg to about 1,000 μg of the GLP-1 molecule.

139. The method of **Claim 138**, wherein an actuation of the device administers about 320 μg to about 500 μg of the GLP-1 molecule.

140. The method of **Claim 123**, wherein the GLP-1 molecule is administered as an aerosol.

141. The method of **Claim 141,** wherein the GLP-1 molecule is delivered from an inhalation device suitable for pulmonary administration and capable of depositing the GLP-1 molecule in the lungs of the patient.

142. The method of **Claim 142**, wherein the device is selected from the group consisting of a nebulizer, a metered-dose inhaler, a dry powder inhaler, and a sprayer.

143. The method of **Claim 123**, wherein the GLP-1 molecule is administered in a pharmaceutically acceptable carrier, in a solution in an aqueous medium, or in a suspension in a non-aqueous medium.

144. The method of **Claim 122** wherein the GLP-1 molecule is GLP-1(7-34), GLP-1(7-35), GLP-1(7-36), GLP-1(7-37), or the amide forms thereof, with at least one modification selected from the group consisting of:

(a) substitution of a glycine, serine, cysteine, threonine, asparagine, glutamine, tyrosine, alanine, valine, isoleucine, leucine, methionine, phenylalanine, arginine, or D-lysine for lysine at position 26 and/or position 34 or substitution of a glycine, serine, cysteine, threonine, asparagine,

glutamine, tyrosine, alanine, valine, isoleucine, leucine, methionine, phenylalanine, lysine, or a D-arginine for arginine at position 36;

(b) substitution of an oxidation-resistant amino acid for tryptophan at position 31;

(c) substitution according to at least one of:
Y for V at position 16;
K for S at position 18;
D for E at position 21;
S for G at position 22;
R for Q at position 23;
R for A at position 24; and
Q for K at position 26;

(d) substitution comprising at least one of:
glycine, serine, or cysteine for alanine at position 8;
aspartic acid, glycine, serine, cysteine, threonine, asparagine, glutamine, tyrosine, alanine, valine, isoleucine, leucine, methionine, or phenylalanine for glutamic acid at position 9;
serine, cysteine, threonine, asparagine, glutamine, tyrosine, alanine, valine, isoleucine, leucine, methionine, or phenylalanine for glycine at position 10; and
glutamic acid for aspartic acid at position 15; and

(e) substitution glycine, serine, cysteine, threonine, asparagine, glutamine, tyrosine, alanine, valine, isoleucine, leucine, methionine, or phenylalanine or the D or N-acylated or alkylated form of histidine for histidine at position 7.

145. The method of **Claim 144,** wherein the GLP-1 analog is acylated at an amino acid side group.

146. The method of **Claim 145,** wherein the GLP-1 analog is acylated on the epsilon-amino group of lysine.

147. The method of **Claim 146,** wherein the lysine that is acylated is lysine 34.

148. The method of **Claim 147,** wherein the acylation is selected from the group consisting of C_6-C_{10} unbranched acyl.

149. The method of **Claim 144**, wherein the GLP-1 molecule is in the form of a dry powder.

150. The method of **Claim 149**, wherein the dry powder has a particle size of about 10 microns mass median aerodynamic diameter.

151. The method of **Claim 150**, wherein the dry powder has a particle size of less than 10 microns mass median aerodynamic diameter.

152. The method of **Claim 151**, wherein the dry powder has a particle size of about 1 to about 5 microns mass median aerodynamic diameter.

153. The method of **Claim 152**, wherein the dry powder has a particle size of about 2 to about 3 microns mass median aerodynamic diameter.

154. The method of **Claim 149**, wherein the GLP-1 molecule is delivered from an inhalation device suitable for pulmonary administration and capable of depositing the GLP-1 molecule in the lungs of the patient.

155. The method of **Claim 154**, wherein the device is selected from the group consisting of a nebulizer, a metered-dose inhaler, a dry powder inhaler, and a sprayer.

156. The method of **Claim 155**, wherein the device is a sprayer or a dry powder inhaler.

157. The method of **Claim 156**, wherein an actuation of the device administers about 40 μg to about 4,000 μg of the GLP-1 molecule.

158. The method of **Claim 157**, wherein an actuation of the device administers about 80 μg to about 2,000 μg of the GLP-1 molecule.

159. The method of **Claim 158**, wherein an actuation of the device administers about 160 μg to about 1,000 μg of the GLP-1 molecule.

160. The method of **Claim 159**, wherein an actuation of the device administers about 320 μg to about 500 μg of the GLP-1 molecule.

161. The method of **Claim 144**, wherein the GLP-1 molecule is administered as an aerosol.

162. The method of **Claim 160**, wherein the GLP-1 molecule is delivered from an inhalation device suitable for pulmonary administration and capable of depositing the GLP-1 molecule in the lungs of the patient.

163. The method of **Claim 161**, wherein the device is selected from the group consisting of a nebulizer, a metered-dose inhaler, a dry powder inhaler, and a sprayer.

164. The method of **Claim 144**, wherein the GLP-1 molecule is administered in a pharmaceutically acceptable carrier, in a solution in an aqueous medium, or in a suspension in a non-aqueous medium.

165. The method of **Claim 122** wherein the GLP-1 molecule is a GLP-1 derivative prepared by the process of acylating a GLP-1 analog selected from the group consisting of GLP-1(7-34), GLP-1(7-35), GLP-1(7-36), GLP-1(7-37), and the amide forms thereof, with at least one modification selected from the group consisting of:

(a) substitution of a glycine, serine, cysteine, threonine, asparagine, glutamine, tyrosine, alanine, valine, isoleucine, leucine, methionine, phenylalanine, arginine, or D-lysine for lysine at position 26 and/or position 34 or substitution of a glycine, serine, cysteine, threonine, asparagine, glutamine, tyrosine, alanine, valine, isoleucine, leucine, methionine, phenylalanine,

lysine, or a D-arginine for arginine at position 36;

(b) substitution of an oxidation-resistant amino acid for tryptophan at position 31;

(c) substitution according to at least one of:
Y for V at position 16;
K for S at position 18;
D for E at position 21;
S for G at position 22;
R for Q at position 23;
R for A at position 24; and
Q for K at position 26;

(d) substitution comprising at least one of:
glycine, serine, or cysteine for alanine at position 8;
aspartic acid, glycine, serine, cysteine, threonine, asparagine, glutamine, tyrosine, alanine, valine, isoleucine, leucine, methionine, or phenylalanine for glutamic acid at position 9;
serine, cysteine, threonine, asparagine, glutamine, tyrosine, alanine, valine, isoleucine, leucine, methionine, or phenylalanine for glycine at position 10; and
glutamic acid for aspartic acid at position 15; and

(e) substitution glycine, serine, cysteine, threonine, asparagine, glutamine, tyrosine, alanine, valine, isoleucine, leucine, methionine, or phenylalanine or the D or N-acylated or alkylated form of histidine for histidine at position 7.

166. The method of **Claim 165** wherein the GLP-1 analog has an arginine substituted for lysine at position 34.

167. The method of **Claim 166** wherein the GLP-1 analog is acylated on the epsilon-amino group of lysine.

168. The method of **Claim 165**, wherein the GLP-1 molecule is in the form of a dry powder.

169. The method of **Claim 168**, wherein the dry powder has a particle size of about 10 microns mass median aerodynamic diameter.

170. The method of **Claim 169**, wherein the dry powder has a particle size of less than 10 microns mass median aerodynamic diameter.

171. The method of **Claim 170**, wherein the dry powder has a particle size of about 1 to about 5 microns mass median aerodynamic diameter.

172. The method of **Claim 171**, wherein the dry powder has a particle size of about 2 to about 3 microns mass median aerodynamic diameter.

173. The method of **Claim 168**, wherein the GLP-1 molecule is delivered from an inhalation device suitable for pulmonary administration and capable of depositing the GLP-1 molecule in the lungs of the patient.

174. The method of **Claim 173**, wherein the device is selected from the group consisting of a nebulizer, a metered-dose inhaler, a dry powder inhaler, and a

sprayer.

175. The method of **Claim 174**, wherein the device is a sprayer or a dry powder inhaler.

176. The method of **Claim 175**, wherein an actuation of the device administers about 40 µg to about 4,000 µg of the GLP-1 molecule.

177. The method of **Claim 176**, wherein an actuation of the device administers about 80 µg to about 2,000 µg of the GLP-1 molecule.

178. The method of **Claim 177**, wherein an actuation of the device administers about 160 µg to about 1,000 µg of the GLP-1 molecule.

179. The method of **Claim 178**, wherein an actuation of the device administers about 320 µg to about 500 µg of the GLP-1 molecule.

180. The method of **Claim 165**, wherein the GLP-1 molecule is administered as an aerosol.

181. The method of **Claim 180**, wherein the GLP-1 molecule is delivered from an inhalation device suitable for pulmonary administration and capable of depositing the GLP-1 molecule in the lungs of the patient.

182. The method of **Claim 181**, wherein the device is selected from the group consisting of a nebulizer, a metered-dose inhaler, a dry powder inhaler, and a sprayer.